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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,697	12/27/2001	Lakshmi Sangameswaran	18136-1055	5363

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EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,697	SANGAMESWARAN, LAKSHMI	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *N/A*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to polynucleotides, classified in class 536, subclass 23.5.

II. Claims 12-14, 17 drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 15, 16 drawn to antibodies, classified in class 530, subclass 388.22.

IV. Claim 18, drawn to methods of gene therapy, classified in class 514, subclass 2.

V. Claims 19, 20, drawn to methods of administering a polypeptide, classified in class 514, subclass 2.

VI. Claims 21, 22, drawn to methods of detecting a polynucleotide, classified in class 435, subclass 6.

VII. Claims 23, 24, drawn to methods of detecting a polypeptide, classified in class 436, subclass 501.

VIII. Claim 25, drawn to methods of identifying binding partners of a polypeptide, classified in class 435, subclass 7.21.

IX. Claim 26, drawn to transgenic animals, classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups I-III are directed to products that are distinct both physically

and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group II, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group II can be used other than to make the protein of Group I, such in the gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group II, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunohistochemical analysis), or therapeutic methods such as those of group V. Although, the protein Group I can be used to identify the ligands of Group VIII, the protein could also be used to produce the antibody of Group III. Although, the DNA of Group I can be used to produce the protein of Group I which can be used to identify the ligands of Group VIII, the DNA could also be used to as a diagnostic probe.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups IV-VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group IV requires a method of gene therapy, which is not required by the other groups. Group V requires a method of administering a polypeptide , which is not required by the other groups. Group VI requires a method of detecting a polynucleotide, which is not required by the other groups. Group VII

requires a method for detecting a polypeptide, which is not required by the other groups. Group VIII requires a method for identifying binding partners or modulators of a polypeptide, which is not required by the other groups.

The polynucleotides of Group I are related to the methods of Groups IV, VI, and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I are patentably distinct from each of the methods of Groups IV, VI, and VIII because the polynucleotides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV, VI, and VIII are materially and functionally distinct from the others. Furthermore, the polynucleotides of Group I and the methods of Group V and VII are patentably distinct because one is not required for the use of the other.

The polypeptides of Group II are related to the methods of Groups V, VII, and VIII as product and process of use. In the instant case the polypeptides of Group II are patentably distinct from each of the methods of Groups V, VII, and VIII because the polypeptides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V, VII, and VIII are materially and functionally distinct from the others. Furthermore, the polypeptides of Group II and the methods of Group IV and VI are patentably distinct because one is not required for the use of the other.

The antibodies of Group III are related to the methods of Group V and VII as product and process of use. In the instant case the antibodies of Group III are patentably distinct from the methods of Group V, VII, and VIII because the antibodies can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V, VII, and VIII are materially and functionally distinct from the others. Furthermore, the antibodies of Group III and the methods of Group IV and VI are patentably distinct because one is not required for the use of the other.

The polynucleotides of Group I and the transgenic animal of Group IX are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP ' 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP ' 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a probe for diagnostic purposes or to produce the polypeptides of Group II and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. The transgenic animal is unrelated to the products and methods of Groups II-VIII because one is not required for the use of the other.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

Claims 1-26 are generic to a plurality of disclosed patentably distinct species comprising polypeptides of 2 and 4, and polynucleotide encoding same. Each polypeptide and each polynucleotide are distinct and divergent molecules, the use of one not being required for the of any other. Furthermore, a search of one could not be relied upon, solely, to provide art that is anticipatory or that might render obvious any other, and to search more than one species in a single application would be unduly burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

August 2, 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER